



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/845,597

04/30/2001

Antoni P. Tomsia

IB-1627

3236

8076

7590

03/27/2009

LAWRENCE BERKELEY NATIONAL LABORATORY
ONE CYCLOTRON ROAD, MAIL STOP 90B
UNIVERSITY OF CALIFORNIA
BERKELEY, CA 94720

EXAMINER

CHRISS, JENNIFER A

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

03/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ANTONI P. TOMSIA, GRAYSON W. MARSHALL,
EDUARDO SAIZ, JOSE M. GOMEZ-VEGA, and
SALLY J. MARSHALL

Appeal 2008-3028
Application 09/845,597¹
Technology Center 1700

Decided:² March 27, 2009

Before JAMES T. MOORE, *Vice Chief Administrative Patent Judge*,
EDWARD C. KIMLIN and MICHAEL P. COLAIANNI, *Administrative
Patent Judges*.

COLAIANNI, *Administrative Patent Judge*.

¹ This Application filed April 30, 2001 (hereinafter "'597 Application"), claims the benefit of priority to Provisional Application No. 60/201,556 filed May 1, 2000 (hereinafter "Provisional Application").

² The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the Decided Date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1, 3, 5, 8 through 12, 20 through 28, and 30, all of the claims pending in the above-identified application. We have jurisdiction pursuant to 35 U.S.C. § 6.

We AFFIRM-IN-PART and enter a new ground of rejection pursuant to 37 C.F.R. § 41.50(b).

STATEMENT OF THE CASE

The subject matter on appeal is directed to a multilayer article. (Claim 1). Further details of the appealed subject matter are recited in claims 1, 3, and 30, which are reproduced below:

1. A multilayer article comprising,
 - a metal substrate,
 - a first layer comprising an inner and outer surface,
 - said first layer comprising a glass composition,
 - said glass composition comprising,
 - 44.2 to 67.7 wt% SiO₂, 10.1 to 23.4 wt% CaO, 5.7 to 13.3 wt% MgO,
 - 10.3 to 23.6 wt% Na₂O, 2.2 to 6.5 wt% K₂O and 6.0 wt% P₂O₅,
 - wherein said glass composition contains hydroxyapatite particles in an amount of up to 50 wt%.
3. The multilayer article of claim 1,
 - wherein there is a first intermediate layer having an inner and outer surface, and said first intermediate layer is located between the substrate and first layer, said first intermediate layer comprising a glass composition as defined in claim 1.
30. The multilayer article of claim 3,

wherein there is a second intermediate layer located between the first intermediate layer and the substrate,
said first layer, first intermediate layer and said second intermediate layer all comprising a glass composition as defined in claim 1,
wherein the SiO₂ concentration is lowest in the first layer, highest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer.

As evidence of unpatentability of the claimed subject matter, the Examiner relies upon the following:

A. Pazo et al., "HA-bioactive Glass Composites: High Temperature Reactivity and 'In-vitro' Behavior," *Scripta Materialia* 34, No. 11, 1729-33, (1996) (hereinafter "Pazo")

J. M. Gomez-Vega et al., "A Multilayer Approach to Fabricate Bioactive Glass Coating on TI Alloys," *Mat. Res. Soc. Symp. Proc.* 550, 349-354, (1999) (hereinafter "the Multilayer article")

J. M. Gomez-Vega et al., "Glass-hydroxyapatite Coatings on Titanium-based Implants," *Bioceramics: Materials and Applications III*, pp. 15-23, (February 2000) (hereinafter "the Glass-hydroxyapatite article")³

U.S. Provisional Application No. 60/201,556, filed May 1, 2000

³ The Examiner's statement (Ans. 2) in the Evidence Relied Upon section of the Answer that the publication date of the Glass-hydroxyapatite article is December 1999 contradicts the Examiner's statement (Ans. 8) in the Response to Argument section of the Answer that "[t]he article used in the rejection was published in February 2000" Additionally, the Examiner states (Ans. 4 and 6) in the two statements of rejection relying upon this article that the publication date is February 2000. Accordingly, we treat the Examiner's December 1999 statement as a misstatement and presume the Examiner finds that the publication date of the Glass-hydroxyapatite article is February 2000.

Appellants appeal the following rejections:

- 1) Claims 1, 8, and 23 under 35 U.S.C. § 102(b) as anticipated by the disclosure of Pazo;
- 2) Claims 1, 3, 5, 8-12, and 20-28 under 35 U.S.C. § 102(b) as anticipated by the disclosure of the Glass-hydroxyapatite article; and
- 3) Claim 30 under 35 U.S.C. § 103(a) as unpatentable over the combined disclosures of the Glass-hydroxyapatite article and the Multilayer article.

With respect to rejection (1), Appellants argue independent claim 1. (Br. 10-11). Appellants do not advance any specific argument regarding the rejection of the remaining claims, which depend from independent claim 1. *Id.* Instead, Appellants refer to their arguments made in connection with the rejection of independent claim 1. *Id.* Accordingly, we address Appellants' arguments with respect to independent claim 1.

With respect to rejections (2) and (3), Appellants argue the claims as groups. (Br. 11). Concerning rejection (3), Appellants proffer no particular argument regarding the features of claim 30, which ultimately depends from claim 1. The Appellants do not proffer any argument specific to a particular claim under rejections (2) and (3). (Br. 11). Rather, Appellants contest the Examiner's refusal to recognize the effective filing date of the '597 Application as the filing date of the Provisional Application. (Br. 11). Accordingly, we select claims 1 and 30 as representative of the groups of claims to address Appellants' arguments regarding rejections (2) and (3). *See* 37 C.F.R. § 41.37(c)(1)(vii).

REJECTION (1) - §102(b) Over the Disclosure of Pazo

ISSUE

With respect to rejection (1), the Examiner finds that Pazo discloses all of the features recited in claim 1. (Ans. 4 and 7). Appellants, on the other hand, argue that Pazo "fail[s] to teach each and every feature of independent Claim 1." (Br. 11). Appellants argue that Pazo's "abstract did not describe a multilayered structure with a metal substrate and a first layer comprising a glass composition, as recited in Claim 1." (Br. 10). Appellants also argue that Pazo, in two of its experiments referenced at page 1733 and at Figures 6 and 7, does not include a metal substrate required by claim 1. (Br. 10).

Thus, the first issue is: Have Appellants shown reversible error in the Examiner's finding that Pazo describes a multilayer article comprising a metal substrate and glass composition as required by claim 1 within the meaning of § 102(b)? We answer this issue in the negative.

FINDINGS OF FACT

1. Appellants do not dispute the Examiner's finding that Pazo's A-3 glass/HA composite corresponds to the recited first layer comprising a glass composition having an inner and outer surface. (*Compare* Ans. 3-4 *with* Br. 10-11). In this regard, Pazo teaches an A-3 glass having, in weight percent, 54.5% SiO₂, 12.0% Na₂O, 4% K₂O, 15% CaO, 8.5% MgO, and 6% P₂O₅. (Pazo, p. 1729). In other words, Pazo's composite is a MgO-containing glass composition.

2. Pazo teaches that a "hot pressed A-3 glass/HA composite . . . is presented in Figure 5." (Pazo, p. 1731). Pazo's Figure 5 description at p. 1732 states, "SEM photograph of the microstructure of the HA/BAG composite obtained by hot pressing . . ."
3. Pazo states that "[t]he presence of HA which is not degraded in the composite assures high bonding strength to the bone." (Pazo, p. 1733). Pazo also states that "[t]he results obtained in the present investigation open the possibility to design new HA-BAG composites with a bioactivity similar to that of bioactive glasses . . ." (Pazo, p. 1732).
4. Pazo does not mention that its HA and MgO-containing BAG glass composite is bonded to a Ti or Ti alloy metal. Pazo states that "MgO-containing BAG . . . combines both high bioactivity and excellent adhesion to Ti and Ti alloys." (Pazo, p. 1729).

PRINCIPLES OF LAW

"A reference anticipates a claim if it discloses the claimed invention 'such that a skilled artisan could take its teachings in *combination with his own knowledge of the particular art and be in possession of the invention.*'" *In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995) (quoting *In re LeGrice*, 301 F.2d 929, 936 (CCPA 1962)).

A factual finding not shown by Appellants to be erroneous may be accepted as fact. *In re Kunzmann*, 326 F.2d 424, 426 n.3 (CCPA 1964).

ANALYSES AND CONCLUSIONS

It is undisputed that Pazo's A-3 glass/HA (hydroxyapatite) composite, which contains, *inter alia*, MgO, meets the recited first layer comprising a glass composition. (FF 1). Pazo also teaches that its A-3 glass is a BAG (bioactive glass). (FF 2). In other words, Pazo teaches a HA/BAG composite containing MgO. (FF 1, 2). In addition, Pazo teaches that its HA/BAG composite assures a high bonding strength to bone (bioactivity). (FF 3).

Although Pazo does not explicitly mention that its HA/BAG composite containing MgO adheres to a Ti or Ti alloy metal, Pazo states that "MgO-containing BAG . . . combines both high bioactivity and excellent adhesion to Ti and Ti alloys." (FF 4).

Thus, we find that Pazo anticipates the claimed invention because Pazo's disclosure puts the public in possession of a multilayered HA/BAG composite containing MgO having a high bioactivity wherein MgO-containing bioactive glass is disclosed as having excellent adhesion to Ti and Ti alloy metals.

Therefore, it follows that Appellants have not shown reversible error in the Examiner's finding that Pazo describes a multilayer article comprising a metal substrate and glass composition as required by claim 1 within the meaning of § 102(b).

Accordingly, based on the factual findings set forth in the Answer and above, we affirm the Examiner's decision rejecting claims 1, 8, and 23 as anticipated by the disclosure of Pazo.

REJECTIONS (2) AND (3) - § 103(a) Rejections Over the Disclosure of the Glass-hydroxyapatite Article and Over the Combined Disclosures of the Glass-hydroxyapatite Article and the Multilayer Article.

STATEMENT OF THE CASE

With respect to rejection (2), the Examiner alleges the Glass-hydroxyapatite article, which has a publication date of February 2000, is available as "prior art" under § 102(b) because its publication date is more than one year prior to the '597 Application's effective filing date. (Ans. 3-4). In doing so, the Examiner alleges that Appellants are not entitled to the Provisional Application's filing date of May 1, 2000, as the '597 Application's effective filing date because the Provisional Application does not have written descriptive support for the entire range of up to 50 wt% hydroxyapatite particles required by claim 1. (Ans. 3 and 7-8). Instead, the Examiner alleges that the '597 Application has an effective filing date of April 30, 2001, which is the filing date of the '597 Application. As such, the Examiner alleges that the Glass-hydroxyapatite article is available as § 102(b) prior art.

Appellants, on the other hand, argue as follows:

The pending application claims priority to U.S. Provisional Application 60/201,556, filed May 1, 2000. As this rejection is based on a reference [i.e., the Glass-hydroxyapatite article] that cannot be considered prior art under 35 U.S.C. § 102(b), Appellants assert that the rejection is moot and should be withdrawn. (Br. 11).

Subsumed in this argument is Appellants' contention⁴ that the Provisional Application has written descriptive support for the claimed range of hydroxyapatite particles (i.e., "up to 50 wt%").

With respect to rejection (3), Appellants do not dispute the Examiner's factual findings regarding either the Glass-hydroxyapatite article or the Multilayer article. (*Compare* Ans. 6-8 with Br. 10-11). Nor do Appellants dispute the Examiner's reason to combine them. (*Compare* Ans. 6-8 with Br. 10-11). Appellants only argue that "[t]he pending application claims priority to U.S. Provisional Application 60/201,556, filed May 1, 2000. As this rejection is based on a reference [i.e., the Glass-hydroxyapatite article] that cannot be considered prior art under [§] 102(b), Appellants assert that the rejection is moot and should be withdrawn." (Br. 11) (emphasis omitted).

ISSUES

⁴ Also subsumed in this argument is Appellants' contention that the Examiner at page 8 in the Answer erred in finding that "Appellant[s] ha[ve] not been granted priority to U.S. Provisional Application 60/201,556, filed May 1, 2000 because . . . the specification of the provisional application does not meet the requirements of a 'specification' according to 37 CFR [§] 1.77 (b) and (c) . . ." Thus, it appears the Appellants contend that their Provisional Application is entitled to a filing date under 37 C.F.R. § 1.53(c). The appropriate avenue for seeking review of an Examiner's determination of a filing date is by petition to the Deputy Commissioner for Patent Examination Policy. *See, e.g. Manual of Patent Examination Procedure* (MPEP) § 1002.02(b), Example 27, (8th ed., Rev. 2, May 2004). As no such review was sought, we note that the Provisional Application's filing date is May 1, 2000, as determined by the Office of Patent Application Processing (formerly known as the Office of Initial Patent Examination).

Have Appellants shown reversible error in the Examiner's finding that Appellants' Provisional Application does not have written descriptive support for the entire range of up to 50 wt% hydroxyapatite particles required by claim 1 such that the effective filing date of the '597 Application is not the Provisional Application's filing date (May 1, 2000) thereby rendering the Glass-hydroxyapatite article available as a printed publication under 35 U.S.C. § 102(b) in rejection (2)? We decide this issue in the affirmative.

Have Appellants shown reversible error in the Examiner's finding that the Glass-hydroxyapatite article is available as a printed publication under 35 U.S.C. § 103(a) via 35 U.S.C. § 102 in rejection (3)? We decide this issue in the negative.

ADDITIONAL FINDINGS OF FACT

5. Table I at page 13 in the Provisional Application is reproduced below:

	Table I Composition and main properties of the synthesized glasses							
	Composition (wt%)						α ($10^{-6}/^{\circ}\text{C}^{\circ}$)	T_g ($^{\circ}\text{C}$)
	SiO_2	Na_2O	CaO	MgO	P_2O_5	K_2O		
6P50	49.8	15.5	15.6	8.9	6.0	4.2	12.2	560
6P53	52.6	10.4	18.0	10.2	6.0	2.8	11.5	608
6P55	54.5	12.0	15.0	8.5	6.0	4.0	11.0	602
6P57	56.5	11.0	15.0	8.5	6.0	3.0	10.8	609
6P61	61.1	10.3	12.6	7.2	6.0	2.8	10.2	624
6P68	67.7	8.3	10.1	5.7	6.0	2.2	8.8	644

α = Coefficient of thermal expansion (measured between 200 and 400 $^{\circ}\text{C}$)

T_s = Softening point

6. The Provisional Application's Table I relates to compositions, in weight percent, of different synthetic glasses. (Provisional Application, pp. 13-14).

7. Table II at page 14 in the Provisional Application is reproduced below:

Table II Multilayered glass coatings results			
Glass layers	Thickness (µm)	Firing T (°C)	Coating results
6P68/6P55	30/20	840	Cracked
6P61/6P55	30/20	820	Good
6P57/6P57	30/20	800	Good
6P57/6P50	30/20	800	Cracked
6P57/6P53/6P50	30/10/10	800	Cracked
6P57/6P57+HA	30/20*	800	Good

*HA:6P57 = 50 wt%

8. The Provisional Application's Table II relates to titanium alloys coated with different synthetic glasses. (Provisional Application, pp. 13-14).
9. Appellants do not dispute the Examiner's findings that the Glass-hydroxyapatite article teaches all of the features recited in claims 1, 3, 5, 8-12, and 20-28. (*Compare* Ans. 4 and 5 with Br. 10-11).
10. The Office of Patent Application Processing (formerly known as the Office of Initial Patent Examination) granted the Provisional Application a filing date of May 1, 2000, based on the submitted Specification and accompanying documentation.

ADDITIONAL PRINCIPLES OF LAW

“The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language.” *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983).

"[T]he PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." *In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976).

A disclosure of a broad range of 25-60% has written descriptive support for a narrower claimed range of "between 35% and 60%" when the Examiner presents no reason to doubt (e.g., showing a distinction in the operability of Appellants' process or the achievement of any desired result) that the disclosure of the broad range describes the narrower claimed range. *In re Wertheim*, 541 F.2d 257, 264 (1976).

35 U.S.C. § 102, in part, states:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or *described in a printed publication* in this or a foreign country, before the invention thereof by the applicant for patent or
- (b) the invention was patented or *described in a printed publication* in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . .

35 U.S.C. § 102(a)-(b) (2008) (emphasis added).

35 U.S.C. § 103, in part, states:

- (a) A patent may not be obtained though the invention is not identically disclosed or *described as set forth in section 102* of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103(a) (2008) (emphasis added).

ANALYSES AND CONCLUSIONS

Rejection (2): The § 102(b) rejection over the disclosure of the Glass-hydroxyapatite article

The Provisional Application's Tables I and II describe a 6P57 glass layer having, in weight percent, a composition of 56.5% SiO₂, 11.0% Na₂O, 3.0% K₂O, 15% CaO, 8.5% MgO, and 6% P₂O₅. (FF 5-8). Because these amounts in the aggregate total 100 wt%, we determine that this 6P57 glass layer has 0 wt% hydroxyapatite particles. (FF 5-8).

The Provisional Application's Tables I and II also describe another glass layer having, in weight percent, a composition of 50 wt% hydroxyapatite particles and 50 wt% 6P57 glass. (FF 5-8).

Thus, the Provisional Application describes, *inter alia*, two different 6P57 glass layers: one having 0 wt% hydroxyapatite and the other having 50 wt% hydroxyapatite. Therefore, we agree with Appellants that the Provisional Application reasonably conveys to one of ordinary skill in the art that Appellants had possession at the time of filing the Provisional Application of the entire range of up to 50 wt% hydroxyapatite particles required by claim 1. *See Wertheim*, 541 F.2d at 264.

Thus, the effective filing date of the '597 Application is the filing date of the Provisional Application (May 1, 2000) thereby rendering the Glass-hydroxyapatite article with a publication date of February 2000 unavailable as a printed publication under § 102(b).

Thus, it follows that Appellants have shown reversible error in the Examiner's finding that Appellants' Provisional Application does not have

written descriptive support for the entire range of up to 50 wt% hydroxyapatite particles required by claim 1. Therefore, the effective filing date of the '597 Application is the Provisional application's filing date (May 1, 2000) thereby rendering the Glass-hydroxyapatite article unavailable as a printed publication under 35 U.S.C. § 102(b) in rejection (2).

Accordingly, for the reasons stated by Appellants in the Brief and above, we reverse the Examiner's decision rejecting claims 1, 3, 5, 8-12, and 20-28 under 35 U.S.C. § 102(b) as anticipated by the disclosure of the Glass-hydroxyapatite article.

Rejection (3): The § 103(a) rejection over the combined disclosures of the Glass-hydroxyapatite article and the Multilayer article

In reference to our above discussion, we agree with Appellants that the Provisional Application reasonably conveys to one of ordinary skill in the art that Appellants had possession of the feature "said glass composition contains hydroxyapatite particles in the amount of up to 50 wt%" recited in independent claim 1. Claim 30 further requires the disputed range by virtue of its ultimate dependency on independent claim 1 at the time of filing the Provisional Application.

This, however, is not the dispositive issue to be resolved in determining whether the Examiner erred in finding that the Glass-hydroxyapatite article is available as "prior art" under 35 U.S.C. § 103(a).

35 U.S.C. § 103(a) allows a rejection to be based on, *inter alia*, prior art that is available under 35 U.S.C. § 102(a) *or* § 102(b). In this case, the February 2000 publication date of the Glass-hydroxyapatite article is before

May 1, 2000, which is the effective filing date of the '597 Application. Thus, the Glass-hydroxyapatite article is available as a printed publication under § 103(a) via § 102(a).

Therefore, it follows that Appellants have not shown reversible error in the Examiner's finding that the Glass-hydroxyapatite article is available as a printed publication under 35 U.S.C. § 103(a) via 35 U.S.C. § 102(a) in rejection (3).

Accordingly, based on the factual findings set forth in the Answer and above, we affirm the Examiner's decision rejecting claim 30 under 35 U.S.C. § 103(a) over the combined disclosures of the Glass-hydroxyapatite article and the Multilayer article.

NEW GROUND OF REJECTION UNDER 37 C.F.R. § 41.50(b)

Claims 1, 3, 5, 8-12, and 20-28 are rejected under 35 U.S.C. § 102(a) as anticipated by the Glass-hydroxyapatite article. As stated above, the Glass-Hydroxyapatite article is available as a printed publication under § 102(a) because the February 2000 publication date of the Glass-hydroxyapatite article is less than one year before May 1, 2000, which is the effective filing date of the '597 Application. In addition, Appellants do not dispute the Examiner's findings that the Glass-hydroxyapatite article teaches all of the claimed features. (FF 9). Because Appellants do not specifically challenge or show error with any of these findings, we accept them as facts. *See Kunzmann*, 326 F.2d at 426 n.3. Accordingly, we enter this new ground of rejection as to claims 1, 3, 5, 8-12, and 20-28.

DECISION

In summary:

1. The § 102(b) rejection of claims 1, 8, and 23 over the disclosure of Pazo is affirmed;
2. The § 102(b) rejection of claims 1, 3, 5, 8-12, and 20-28 over the disclosure of the Glass-hydroxyapatite article is reversed;
3. The § 103(a) rejection of claim 30 over the combined disclosures of the Glass-hydroxyapatite article and the Multilayer article is affirmed; and
4. A new ground of rejection pursuant to 37 C.F.R. § 41.50(b) of claims 1, 3, 5, 8-12, and 20-28 under § 102(a) over the Glass-hydroxyapatite article has been added.

TIME PERIOD

37 C.F.R. § 41.50(b) in part states "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." 37 C.F.R. § 41.50(b) also provides that Appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

- (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

Appeal 2008-3028
Application 09/845,597

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

AFFIRMED-IN-PART and NEW GROUND OF REJECTION pursuant to
37 C.F.R. § 41.50(b)

cam

LAWRENCE BERKELEY NATIONAL LABORATORY
ONE CYCLOTRON ROAD,
MAIL STOP 90B
UNIVERSITY OF CALIFORNIA
BERKELEY CA 94720